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consisting of a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, and an enzyme.

- 56. (New) The method of claim 51, wherein said cellular component is taken from the subject's kidney.
  - 57. (New) The method of claim 51, wherein said cellular component is a protein.

#### **REMARKS**

Claims 15, 22, 25-29, 33-34, 48 and 49 are pending in the instant application. Claims 15 and 22 are amended to clearly set forth the nature of the claimed invention and to obviate the indefiniteness rejection. Claims 29 and 33-34 are cancelled. New claims 50-57 encompassing antibody directed against RCNL-1 protein and its immunogenic fragments are added. Support for the newly added claims and amendments do not go beyond the original disclosure of the application. Accordingly, claims 15, 22, 25, 48 and 49, 50-57 are presented for reconsideration and reexamination which are respectfully requested in view of the foregoing amendments and following remarks.

#### REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner has maintained her indefiniteness rejection of claims 15, 22, 25-29, and 33-34. Specifically, the Examiner alleged that the claimed invention reads on "a genus of antibodies targeted to a broad genus of nuclear matrix proteins and fragments thereof." In addition, the claimed polypeptides "encompass all corresponding proteins from other species, mutated forms...and so forth." Furthermore, the claimed antibodies are "capable of binding to fragments of the claimed renal matrix proteins that cover isolated fragments and fragments of the claimed proteins embedded within another protein." Applicant respectfully traverses this rejection.

To advance prosecution, Applicant has amended claim 15 by excluding the antibody directed to RCNL-1, amended claims 15 and 22 to encompass antibodies against human renal nuclear matrix proteins and immunogenic fragments thereof, cancelled claims 29 and 33-34,

and presented new claims 50-57 directed to RCNL-1. Support for the above amendments is found throughout the specification, particularly at page 8, line 32-34 and page 10 (for the term "immunogenic"), lines 13-14 (for a human subject).

Applicant submits that the above rejection has been obviated and rendered moot. In light of this amendment and foregoing remarks, reconsideration and withdrawal of the rejection is respectfully requested.

#### REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

At page 3, section 3 of the Office Action, the Examiner rejected claims 29 and 33-34, under section 112, first paragraph, on the ground that the specification fails to provide sufficient guidance or instructions that would enable one of skill in the art to use the claimed antibodies without undue experimentation.

Without acquiescing to the above rejection, Applicant chooses to cancel claims 29 and 33-34 to advance prosecution of the present application and reserves the right to pursue a divisional application based on the subject matter of the cancelled claims.

## **DOUBLE PATENTING**

In section 4, page 6 of the Office Action, the Examiner rejected claims 22, 25-28 and 48-49 under the doctrine of obviousness-type double patenting as being unpatentable over claims 2-4 and 15 of the parent application, U.S. Patent No. 6,232,443 ('443 patent). Applicant respectfully traverse this rejection.

It is improper for the Examiner to issue the above rejection because 35 U.S.C § 121 prohibits a double patenting rejection if the instant application was filed as a result of a restriction requirement issued by the Office. The present application is a divisional application of the '443 patent and the pending claims were withdrawn as non-elected claims during the prosecution of the '443 patent. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of this rejection.

# **CONCLUSION**

In view of the foregoing amendments and remarks, favorable reconsideration and allowance of this application are requested. An early notice in this regard is earnestly solicited. In the event that any issues remain, the Examiner is invited to contact the undersigned with any proposal to expedite prosecution.

Respectfully submitted,

Date

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

### MARKED UP VERSION SHOWING CHANGES MADE

- 15. (Thrice Amended) An antibody [which binds to] <u>directed against</u> a <u>renal</u> nuclear matrix protein or [a] <u>an immunogenic</u> fragment thereof <u>in a human subject</u>, <u>wherein said protein is absent in normal renal cells but present in cancerous renal cells and is selected from the group consisting of:</u>
  - (a) RCCA-1 having a molecular weight of about 53 kD and a pI of about 9.30;
  - (b) RCCA-2 having a molecular weight of about 32 kD and a pI of about 6.95;
  - (c) RCCA-3 having a molecular weight of about 27 kD and a pI of about 6.50;
  - (d) RCCA-4 having a molecular weight of about 20 kD and a pI of about 5.25; and
- (e) RCCA-5 having a molecular weight of about 15 kD and a pI of about 6.00 or an immunogenic fragment thereof[; and]
  - [(f) RCNL-1 having a molecular weight of about 103 kD and a pI of about 8.30,

said nuclear matrix protein is present in normal renal cells but absent in cancerous renal cells, or absent in normal renal cells but present in cancerous renal cells].

22. (Thrice amended) A method for detecting a cell proliferative disorder in a <u>human</u> subject, comprising contacting a cellular component from [the] <u>said</u> subject with said antibody of claim 15, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component.